

Version: May2011
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Battelle Columbus Laboratory	059902805	09/16/02	729	50(1)	21(676)	506.2	bis(2-Chloroethoxy)methane
Battelle Columbus Laboratory	059700307	07/10/02	728	50(1)	25(680)	510.4	1,2-Dibromo-2,4-dicyanobutane
Southern Research Institute	059500305	04/05/04	729	50(1)	27(683)	508.5	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903203	09/15/04	727	50(1)	23(651)	510.1	Pyrogallol
Female							
Battelle Columbus Laboratory	059902805	09/17/02	730	50(1)	19(646)	341.0	bis(2-Chloroethoxy)methane
Battelle Columbus Laboratory	059700307	07/11/02	729	50(1)	29(695)	337.8	1,2-Dibromo-2,4-dicyanobutane
Southern Research Institute	059500305	04/05/04	732	50(1)	30(685)	356.2	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903203	09/16/04	728	50(1)	29(670)	351.0	Pyrogallol

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		Male			Female		
#All Organs:							
Benign Tumors							
		49/50 (98%)	46/50 (92%)	46/50 (92%)	37/50 (74%)	46/50 (92%)	47/50 (94%)
		47/50 (94%)			43/50 (86%)		
Overall Incidence	Total	188/200 (94%)	Mean 94%	SD 2.83%	Total	173/200 (86.5%)	Mean 86.5% SD 9%
.....							
#All Organs:							
Malignant Tumors							
		26/50 (52%)	23/50 (46%)	33/50 (66%)	19/50 (38%)	15/50 (30%)	22/50 (44%)
		22/50 (44%)			12/50 (24%)		
Overall Incidence	Total	104/200 (52%)	Mean 52%	SD 9.93%	Total	68/200 (34%)	Mean 34% SD 8.79%
.....							
#All Organs:							
Malignant and Benign Tumors							
		49/50 (98%)	50/50 (100%)	48/50 (96%)	44/50 (88%)	48/50 (96%)	49/50 (98%)
		49/50 (98%)			45/50 (90%)		
Overall Incidence	Total	196/200 (98%)	Mean 98%	SD 1.63%	Total	186/200 (93%)	Mean 93% SD 4.76%
.....							
#All Organs:							
Hemangioma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)			0/50 (0%)		
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Hemangiosarcoma							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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		Male				Female			
#All Organs:									
Hemangiosarcoma or Hemangioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Histiocytic Sarcoma									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#All Organs:									
Leukemia: Erythrocytic									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated									
		17/50 (34%)	17/50 (34%)	26/50 (52%)		12/50 (24%)	10/50 (20%)	18/50 (36%)	
		11/50 (22%)				8/50 (16%)			
Overall Incidence	Total	71/200 (35.5%)	Mean 35.5%	SD 12.37%	Total	48/200 (24%)	Mean 24%	SD 8.64%	
.....									
#All Organs:									
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

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#: Denominator is number of animals necropsied

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		Male				Female			
#All Organs:									
Mesothelioma: Benign									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Mesothelioma: Benign, Malignant, NOS									
		2/50 (4%)	1/50 (2%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	9/200 (4.5%)	Mean 4.5%	SD 2.52%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Mesothelioma: Malignant									
		2/50 (4%)	0/50 (0%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	8/200 (4%)	Mean 4%	SD 3.27%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#All Organs:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	

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		Male				Female			
#All Organs:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Adrenal Cortex:									
Adenoma									
		0/50 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	4/50 (8%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%	
.....									
*Adrenal Cortex:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla:									
Ganglioneuroma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	

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		Male				Female			
*Adrenal Medulla:									
Pheochromocytoma Benign									
		3/50 (6%)	5/50 (10%)	11/49 (22%)		1/50 (2%)	1/50 (2%)	1/49 (2%)	
		4/50 (8%)				1/50 (2%)			
Overall Incidence	Total	23/199 (11.56%)	Mean 11.61%	SD 7.41%	Total	4/199 (2.01%)	Mean 2.01%	SD 0.02%	
.....									
*Adrenal Medulla:									
Pheochromocytoma Complex									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla:									
Pheochromocytoma Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla:									
Pheochromocytoma: Benign, Complex, Malignant, NOS									
		3/50 (6%)	5/50 (10%)	11/49 (22%)		1/50 (2%)	1/50 (2%)	1/49 (2%)	
		5/50 (10%)				1/50 (2%)			
Overall Incidence	Total	24/199 (12.06%)	Mean 12.11%	SD 7.14%	Total	4/199 (2.01%)	Mean 2.01%	SD 0.02%	
.....									
#Bone:									
Chordoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

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		Male				Female			
#Bone:									
Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Bone:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Brain:									
Astrocytoma Malignant									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Ependymoma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

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		Male				Female			
*Brain:									
Ependymoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Glioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Glioma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Glioma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Granular Cell Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

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#: Denominator is number of animals necropsied

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		Male				Female			
*Brain:									
Oligodendroglioma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Oligodendroglioma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Brain:									
Oligodendroglioma, Glioma, or Astrocytoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Brain:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Schwannoma Malignant									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	

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		Male				Female			
*Clitoral/Preputial Gland:									
Adenoma									
		2/50 (4%)	2/50 (4%)	1/50 (2%)		2/50 (4%)	6/50 (12%)	6/50 (12%)	
		0/50 (0%)				3/50 (6%)			
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 1.91%	Total	17/200 (8.5%)	Mean 8.5%	SD 4.12%	
.....									
*Clitoral/Preputial Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	3/50 (6%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	Total	4/200 (2%)	Mean 2%	SD 2.83%	
.....									
*Clitoral/Preputial Gland:									
Carcinoma or Adenoma									
		2/50 (4%)	2/50 (4%)	4/50 (8%)		2/50 (4%)	6/50 (12%)	9/50 (18%)	
		0/50 (0%)				4/50 (8%)			
Overall Incidence	Total	8/200 (4%)	Mean 4%	SD 3.27%	Total	21/200 (10.5%)	Mean 10.5%	SD 5.97%	
.....									
*Clitoral/Preputial Gland:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Ear:									
Neural Crest Tumor									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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		Male				Female			
#Esophagus:									
Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Eye:									
Melanoma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Eye:									
Melanoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Eye:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Harderian Gland:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
#Harderian Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Harderian Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%	
.....									
*Heart:									
Schwannoma Benign									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Heart:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Large: Colon/Rectum:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
#Intestine Large: Colon/Rectum:									
 Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
#Intestine Large: Colon/Rectum:									
 Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Duodenum:									
 Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Duodenum:									
 Leiomyoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Duodenum:									
 Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
#Intestine Small: Ileum:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Intestine Small: Jejunum:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum:									
Granular Cell Tumor Malignant									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum:									
Leiomyoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
#Intestine Small: Site Unspecified: Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Intestine Small: Site Unspecified: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Intestine Small: Site Unspecified: Granular Cell Tumor Malignant									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified: Leiomyoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
#Intestine Small: Site Unspecified:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Islets, Pancreatic:									
Adenoma									
		3/50 (6%)	6/50 (12%)	5/49 (10%)		0/50 (0%)	0/50 (0%)	3/49 (6%)	
		3/50 (6%)				2/50 (4%)			
Overall Incidence	Total	17/199 (8.54%)	Mean 8.55%	SD 3.04%	Total	5/199 (2.51%)	Mean 2.53%	SD 3.05%	
.....									
*Islets, Pancreatic:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	3/49 (6%)		1/50 (2%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/199 (1.51%)	Mean 1.53%	SD 3.06%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Islets, Pancreatic:									
Carcinoma or Adenoma									
		3/50 (6%)	6/50 (12%)	8/49 (16%)		1/50 (2%)	0/50 (0%)	3/49 (6%)	
		3/50 (6%)				2/50 (4%)			
Overall Incidence	Total	20/199 (10.05%)	Mean 10.08%	SD 5.03%	Total	6/199 (3.02%)	Mean 3.03%	SD 2.63%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
*Kidney: Pelvis and Transitional Epithelium: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Pelvis and Transitional Epithelium: Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
*Kidney: Renal Tubule: Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Lipoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Kidney: Renal Tubule: Mesenchymal Tumor Benign									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Mesenchymal Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
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		Male				Female			
*Kidney: Renal Tubule:									
 Nephroblastoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule:									
 Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Liver:									
 Cholangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
 Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
 Hepatocellular Adenoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				2/50 (4%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	2/200 (1%)	Mean 1%	SD 2%	

#: Denominator is number of animals with tissues examined microscopically

*: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
*Liver:									
Hepatocellular Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatoblastoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatocellular Adenoma									
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				2/50 (4%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	2/200 (1%)	Mean 1%	SD 2%	
.....									
*Liver:									
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma									
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				2/50 (4%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	2/200 (1%)	Mean 1%	SD 2%	
.....									
*Liver:									
Ito Cell Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
*Lung:									
Alveolar/Bronchiolar Adenoma									
		4/50 (8%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	4/50 (8%)	1/50 (2%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	8/200 (4%)	Mean 4%	SD 2.83%	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		3/50 (6%)				0/50 (0%)			
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma									
		5/50 (10%)	2/50 (4%)	2/50 (4%)		0/50 (0%)	4/50 (8%)	1/50 (2%)	
		4/50 (8%)				0/50 (0%)			
Overall Incidence	Total	13/200 (6.5%)	Mean 6.5%	SD 3%	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%	
.....									
*Lung:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Lung:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

#: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
*Lung:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland:									
Adenolipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/200 (2%)	Mean 2%	SD 1.63%	
.....									
#Mammary Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	6/200 (3%)	Mean 3%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
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		Male				Female			
#Mammary Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	3/50 (6%)	3/50 (6%)	
		1/50 (2%)				3/50 (6%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	10/200 (5%)	Mean 5%	SD 2%	
.....									
#Mammary Gland:									
Fibroadenoma									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		16/50 (32%)	14/50 (28%)	19/50 (38%)	
		0/50 (0%)				24/50 (48%)			
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	73/200 (36.5%)	Mean 36.5%	SD 8.7%	
.....									
#Mammary Gland:									
Fibroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma or Adenoma									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		16/50 (32%)	15/50 (30%)	19/50 (38%)	
		0/50 (0%)				25/50 (50%)			
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	75/200 (37.5%)	Mean 37.5%	SD 9%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		17/50 (34%)	17/50 (34%)	21/50 (42%)	
		1/50 (2%)				26/50 (52%)			
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%	Total	81/200 (40.5%)	Mean 40.5%	SD 8.54%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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 Tumor Incidence for Selected Control Animal Groups
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		Male				Female			
#Mesentery:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 2%	
.....									
*Nose:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/48 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
*Nose:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/48 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Papilloma Squamous or Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Oral Mucosa:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
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		Male				Female			
#Oral Mucosa:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Ovary:									
Cystadenoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Ovary:									
Fibrosarcoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Ovary:									
Granulosa Cell Tumor Benign									
						0/50 (0%)	0/50 (0%)	1/50 (2%)	
						1/50 (2%)			
Overall Incidence	Total				Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
*Ovary:									
Granulosa Cell Tumor Malignant									
						1/50 (2%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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	Male	Female
*Ovary:		
Granulosa Cell Tumor: Benign, Malignant, NOS		
	1/50 (2%)	0/50 (0%)
	1/50 (2%)	1/50 (2%)
Overall Incidence	Total 3/200 (1.5%)	Mean 1.5% SD 1%
.....		
*Ovary:		
Granulosa-Theca Tumor Benign		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%
.....		
*Ovary:		
Granulosa-Theca Tumor Malignant		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%
.....		
*Ovary:		
Schwannoma Malignant		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%
.....		
*Ovary:		
Tubulostromal Adenoma		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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		Male				Female			
*Pancreas:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Mixed Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Mixed Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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		Male				Female			
*Parathyroid Gland:									
Adenoma									
		0/49 (0%)	0/49 (0%)	0/49 (0%)		0/43 (0%)	0/46 (0%)	1/50 (2%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	1/188 (0.53%)	Mean 0.5%	SD 1%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
		35/49 (71%)	32/50 (64%)	33/50 (66%)		22/50 (44%)	35/50 (70%)	31/50 (62%)	
		33/50 (66%)				25/50 (50%)			
Overall Incidence	Total	133/199 (66.83%)	Mean 66.86%	SD 3.19%	Total	113/200 (56.5%)	Mean 56.5%	SD 11.7%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma									
		0/49 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	2/200 (1%)	Mean 1%	SD 2%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma or Adenoma									
		35/49 (71%)	32/50 (64%)	35/50 (70%)		22/50 (44%)	35/50 (70%)	33/50 (66%)	
		33/50 (66%)				25/50 (50%)			
Overall Incidence	Total	135/199 (67.84%)	Mean 67.86%	SD 3.45%	Total	115/200 (57.5%)	Mean 57.5%	SD 12.48%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Ganglioneuroma									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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		Male				Female			
*Pituitary Gland: Pars Intermedia:									
Adenoma									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Pituitary Gland: Pars Intermedia:									
Carcinoma or Adenoma									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Pituitary Gland: Pars Nervosa:									
Craniopharyngioma									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Prostate:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%					
.....									
*Prostate:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%					

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
*Salivary Glands:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Salivary Glands:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Salivary Glands:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Salivary Glands:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Seminal Vesicle:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%					

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
#Skeletal Muscle:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle:									
Hemangiosarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle:									
Rhabdomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skeletal Muscle:									
Rhabdomyosarcoma or Rhabdomyoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Basal Cell Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
#Skin:									
Basal Cell Adenoma or Basosquamous Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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	Male				Female			
#Skin:								
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma								
		2/50 (4%)	2/50 (4%)	7/50 (14%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		3/50 (6%)				1/50 (2%)		
Overall Incidence	Total	14/200 (7%)	Mean 7%	SD 4.76%	Total	2/200 (1%)	Mean 1%	SD 1.15%
.....								
#Skin:								
Fibroma								
		1/50 (2%)	7/50 (14%)	5/50 (10%)		2/50 (4%)	0/50 (0%)	3/50 (6%)
		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	14/200 (7%)	Mean 7%	SD 6%	Total	6/200 (3%)	Mean 3%	SD 2.58%
.....								
#Skin:								
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma								
		3/50 (6%)	8/50 (16%)	7/50 (14%)		2/50 (4%)	0/50 (0%)	3/50 (6%)
		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	19/200 (9.5%)	Mean 9.5%	SD 6.61%	Total	6/200 (3%)	Mean 3%	SD 2.58%
.....								
#Skin:								
Fibrosarcoma								
		2/50 (4%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.31%	Total	0/200 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma								
		2/50 (4%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
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		Male				Female			
#Skin:									
Fibrous Histiocytoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Keratoacanthoma									
		0/50 (0%)	2/50 (4%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	8/200 (4%)	Mean 4%	SD 3.27%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Lipoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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		Male				Female			
#Skin:									
Liposarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Neural Crest Tumor									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Neural Crest Tumor, Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Neurofibroma or Schwannoma benign									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Neurofibrosarcoma or Schwannoma (malignant or NOS)									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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 Tumor Incidence for Selected Control Animal Groups
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		Male				Female			
#Skin:									
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)									
		1/50 (2%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Schwannoma Benign									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Schwannoma Malignant									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Squamous Cell Carcinoma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
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		Male				Female			
#Skin:									
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
#Skin:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma or Papilloma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		1/50 (2%)	2/50 (4%)	6/50 (12%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		3/50 (6%)				0/50 (0%)			
Overall Incidence	Total	12/200 (6%)	Mean 6%	SD 4.32%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		0/50 (0%)	2/50 (4%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		3/50 (6%)				0/50 (0%)			
Overall Incidence	Total	10/200 (5%)	Mean 5%	SD 4.16%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
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		Male				Female			
#Skin:									
Trichoepithelioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin: Sebaceous Gland:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin: Sebaceous Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Spinal Cord:									
Astrocytoma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Spinal Cord:									
Astrocytoma Malignant									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
#Spinal Cord:									
 Glioma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
 Fibrosarcoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
 Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
 Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
 Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
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Route: SKIN
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		Male				Female			
*Spleen:									
Sarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Squamous Cell Papilloma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
#Stomach, Glandular:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Glandular:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Glandular:									
Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Glandular:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Testes:									
Adenoma									
		30/50 (60%)	37/50 (74%)	34/50 (68%)					
		37/50 (74%)							
Overall Incidence	Total	138/200 (69%)	Mean 69%	SD 6.63%					

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
*Testes:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		1/50 (2%)							
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					
.....									
*Thymus:									
Thymoma Benign									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/45 (0%)	1/50 (2%)	
		0/47 (0%)				1/50 (2%)			
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	2/194 (1.03%)	Mean 1%	SD 1.15%	
.....									
*Thymus:									
Thymoma Malignant									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/45 (0%)	0/50 (0%)	
		0/47 (0%)				0/50 (0%)			
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%	
.....									
*Thymus:									
Thymoma NOS									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/45 (0%)	0/50 (0%)	
		0/47 (0%)				0/50 (0%)			
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%	
.....									
*Thymus:									
Thymoma: Benign, Malignant, NOS									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/45 (0%)	1/50 (2%)	
		0/47 (0%)				1/50 (2%)			
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	2/194 (1.03%)	Mean 1%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male			Female		
*Thyroid Gland: C-Cell: Adenoma							
		10/50 (20%) 9/50 (18%)	10/50 (20%)	6/46 (13%)	6/50 (12%) 7/50 (14%)	8/50 (16%)	7/50 (14%)
Overall Incidence	Total	35/196 (17.86%)	Mean 17.76%	SD 3.28%	Total	28/200 (14%)	Mean 14% SD 1.63%
.....							
*Thyroid Gland: C-Cell: Carcinoma							
		1/50 (2%) 0/50 (0%)	2/50 (4%)	0/46 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/196 (1.53%)	Mean 1.5%	SD 1.91%	Total	1/200 (0.5%)	Mean 0.5% SD 1%
.....							
*Thyroid Gland: C-Cell: Carcinoma or Adenoma							
		11/50 (22%) 9/50 (18%)	12/50 (24%)	6/46 (13%)	6/50 (12%) 7/50 (14%)	8/50 (16%)	8/50 (16%)
Overall Incidence	Total	38/196 (19.39%)	Mean 19.26%	SD 4.84%	Total	29/200 (14.5%)	Mean 14.5% SD 1.91%
.....							
*Thyroid Gland: Follicular Cell: Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5% SD 1%
.....							
*Thyroid Gland: Follicular Cell: Carcinoma							
		0/50 (0%) 0/50 (0%)	1/50 (2%)	2/46 (4%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/196 (1.53%)	Mean 1.59%	SD 2.07%	Total	1/200 (0.5%)	Mean 0.5% SD 1%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 05/18/2011

		Male				Female			
*Thyroid Gland: Follicular Cell:									
Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	2/46 (4%)		2/50 (4%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	3/196 (1.53%)	Mean 1.59%	SD 2.07%	Total	4/200 (2%)	Mean 2%	SD 1.63%	
.....									
#Tissue NOS:									
Paranglioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Tongue:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Tongue:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Tongue:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 05/18/2011

		Male				Female			
#Tooth:									
Adamantinoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Tooth:									
Odontoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Urinary Bladder:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Urinary Bladder:									
Carcinoma or Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Urinary Bladder:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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		Male				Female			
*Urinary Bladder:									
Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Uterus:									
Adenoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Uterus:									
Carcinoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Uterus:									
Deciduoma Benign									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Uterus:									
Leiomyosarcoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 05/18/2011

	Male	Female
#Uterus: Polyp Stromal		
	5/50 (10%) 7/50 (14%)	2/50 (4%) 10/50 (20%)
Overall Incidence	Total 24/200 (12%)	Mean 12% SD 6.73%
#Uterus: Sarcoma		
	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 1/200 (0.5%)	Mean 0.5% SD 1%
#Uterus: Sarcoma Stromal		
	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total 2/200 (1%)	Mean 1% SD 1.15%
#Uterus: Sarcoma Stromal or Polyp Stromal		
	6/50 (12%) 7/50 (14%)	3/50 (6%) 10/50 (20%)
Overall Incidence	Total 26/200 (13%)	Mean 13% SD 5.77%
#Uterus: Schwannoma Malignant		
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 05/18/2011

					Male		Female				
#Vagina:											
Polyp											
					0/50	(0%)	0/50	(0%)	0/50	(0%)	
					0/50	(0%)					
Overall Incidence					Total	0/200	(0%)	Mean	0%	SD	0%
.....											
#Vagina:											
Sarcoma											
					0/50	(0%)	0/50	(0%)	0/50	(0%)	
					0/50	(0%)					
Overall Incidence					Total	0/200	(0%)	Mean	0%	SD	0%
.....											
#Vagina:											
Schwannoma Malignant											
					0/50	(0%)	0/50	(0%)	0/50	(0%)	
					0/50	(0%)					
Overall Incidence					Total	0/200	(0%)	Mean	0%	SD	0%
.....											
#Zymbal's Gland:											
Adenoma											
		1/50	(2%)	0/50	(0%)	0/50	(0%)			0/50	(0%)
		0/50	(0%)					0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/200 (0.5%)		Mean	0.5%	SD	1%	Total	0/200	(0%)	Mean 0% SD 0%
.....											
#Zymbal's Gland:											
Carcinoma											
		0/50	(0%)	0/50	(0%)	1/50	(2%)			0/50	(0%)
		1/50	(2%)					0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/200 (1%)		Mean	1%	SD	1.15%	Total	0/200	(0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ETHANOL

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 Report Date: 05/18/2011

		Male				Female								
#Zymbal's Gland:														
Carcinoma or Adenoma														
		1/50	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)			
		1/50	(2%)					0/50	(0%)					
Overall Incidence	Total	3/200 (1.5%)		Mean	1.5%	SD	1%	Total	0/200 (0%)		Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied